# KUROS TO PRESENT POSITIVE KUR-115 PRECLINICAL DATA FOR INTERBODY SPINAL FUSION TREATMENT AT THE 2015 NORTH AMERICAN SPINE SOCIETY

**Zurich, Switzerland, 15th October 2015** - Kuros Biosurgery AG, a biotechnology company developing novel biomaterials and bioactive-biomaterial combination products, today announces that positive pre-clinical data assessing the potential of KUR-115 as a lumbar interbody spinal fusion treatment will be presented today at the 2015 North American Spine Society (NASS) event in Chicago, Illinois, by Dr. Bryan W. Cunningham. Dr. Cunningham was lead investigator of the study which was carried out at the Orthopaedic Spinal Research Institute, University of Maryland.

The objective of the study was to evaluate and compare the efficacy of KUR-115 in various concentrations versus autograft and bone morphogenetic protein-2 (BMP-2) controls for lumbar interbody spinal arthrodesis.

The study achieved its primary objective which was the demonstration of a fusion identified at 4 and 10 months in 8/8 levels treated with the optimal concentration of KUR-115 (0.4 mg/mL) as well as the autograft and BMP-2 controls; all following a direct lateral surgical approach, complete diskectomy and endplate decortication at L2-L3 and L4-L5.

Flexion-extension and lateral bending exhibited reduced segmental motion for all treatment groups at 4 months *versus* the non-operative intact spine ($p<0.05$). By 12 months, both axial rotation and flexion-extension motion were significantly lower than the intact spine ($p<0.05$). Histopathology indicated no evidence of foreign body/inflammatory reaction or significant pathological changes in any specimens.

There were also no significant intra-or peri-operative complications in any cases.

**Dr. Bryan W. Cunningham** commented: “These positive pre-clinical results suggest that KUR-115 could be a highly effective alternative to autograft in lumbar interbody spinal arthrodesis. This study will serve as a basic scientific basis for future clinical investigations into the use and efficacy of parathyroid hormone based approaches for the treatment of a number of spinal indications.”

**Didier Cowling, Chief Executive Officer**, said: "These positive results further highlight the significant potential of Kuros’ technology platform in a broad range of spinal and orthopaedic indications. We look forward to progressing KUR-115 into clinical development and adding to the positive data generated in large Phase IIb studies by KUR-111 and KUR-113.”

The pre-clinical study was performed on 32 skeletally mature sheep and randomized into post-operative time periods of 4 months (n=20) and 10 months (n=12). Treatment was administered using rectangular PEEK cages (sample size of n=8) prefilled with the following treatments per time period: 4 Month Treatments – KUR-115 at 0.2 mg/ml, 0.4 mg/ml and 0.7mg/ml in a fibrin matrix, autograft and bone morphogenetic protein-2 (BMP-2). 10 Month Treatments - KUR-115 at 0.4 mg/ml in fibrin, autograft and BMP-2.

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**About KUR-115:**
KUR-115 is composed of a variant of parathyroid hormone (vPTH) and fibrin sealant. The product has been developed to combine a high level of efficacy with ease of use and safety.

**About Kuros:**
Kuros is focused on the development of novel biomaterials and bioactive-biomaterial combination products in therapeutic areas covering sealants and orthobiologics.

Kuros has a late stage pipeline which has generated highly encouraging data in multiple clinical studies. Its most advanced sealant product candidate is KUR-023, a sealant that has successfully completed European clinical development and is close to being CE Marked. KUR-111 and KUR-113, Kuros' most advanced orthobiologic products have both met the primary endpoints in large well controlled Phase II clinical studies and are progressing towards Phase III.

Kuros has two biomaterial technology platforms, one based on fibrin sealants and the other based on its own proprietary synthetic technology that can mimic fibrin in many of its attributes. These materials can be used alone or in combination with biologically active molecules, and can be delivered in many forms including as injectable liquids, sprays, gels, pastes or preformed implants. The incorporation of the biologically active molecules into the matrices aims to maximize their activity by retention at the site of action. Kuros has a number of methodologies to achieve the desired retention and release profiles of the biologically active molecules. The products are designed to combine ease of application with localized delivery.

The company is located in Zurich, Switzerland.

For more information, visit: www.kuros.ch

**Press Enquiries:**


Kuros
Didier Cowling, CEO +41 (0)44 200 56 00
Alistair Irvine, CBO +41 (0)44 200 56 00

For International Media Enquires:
Citigate Dewe Rogerson david.dible@citigatedr.co.uk
David Dible, Sylvie Berrebi +44 (0)207 638 9571